plaintiffs argue that the Fifth Circuit's decision in their case creates a conflict with that court's earlier ruling in *Moss v. Merck & Co.*, 381 F.3d 501 (5th Cir. 2004), a brief examination of that precedent distinguishes it from this case. This case concerns a claim seeking compensation for an alleged vaccine-related injury suffered by a recipient of a vaccine. *Moss* involved a claim brought by parent plaintiffs for loss of consortium-type damages not compensable under the Vaccine Act.

The Vaccine Court is an administrative tribunal entrusted by Congress with exclusive original jurisdiction over certain vaccine-related personal injury claims. If a claimant is qualified to file a petition in Vaccine Court, he must do so, and no other state or federal court has jurisdiction over a civil action against vaccine manufacturers arising from the vaccine-related injury until he exhausts his remedies. The Vaccine Act allows claimants dissatisfied with a decision rendered in Vaccine Court to seek review in the United States Court of Federal Claims and in the United States Court of Appeals for the Federal Circuit. The Act also gives claimants the option of rejecting the decision—whether favorable or unfavorable—and filing suit in a court of general jurisdiction.

Plaintiffs argue that their qualification to file in Vaccine Court may be adjudicated as part of a civil action in tort, brought without having first petitioned in Vaccine Court and exhausting that remedy. Thus, plaintiffs contend that they are entitled to litigate a dispute about their qualification in federal district court in the first instance. The Fifth Circuit correctly rejected this argument. It found that plaintiffs' failure to present their claim—including their qualification to file a petition—in Vaccine Court in the first instance constituted a failure to exhaust administrative remedies that

barred the district court from exercising jurisdiction. This decision is supported by the Vaccine Act itself, which expressly makes the Vaccine Court the initial forum for presenting any issues arising from a claim of vaccine-related injury, including alleged disputes over whether a claimant meets the statutory qualifications for the program. It is further supported by the settled principle of administrative law that agencies and administrative tribunals have the initial authority to determine their own jurisdiction unless jurisdiction is plainly lacking.

The wisdom of that principle is perfectly illustrated by this case. Plaintiffs waited nine years after the Vaccine Act statute of limitations expired to claim that they were exempt from the Vaccine Act. Without first filing a Vaccine Court petition, plaintiffs filed a civil action in federal district court. When Wyeth raised the issue of non-compliance with the Vaccine Act, plaintiffs argued that they had not been qualified to file a petition under the Act. Their argument relied on a provision of the Vaccine Act that had since been repealed. Conveniently for plaintiffs, the only "evidence" available for the court to consider consisted of incomplete billing records, plaintiffs' self-serving, conclusory affidavits, and speculation about nine-year-old Texas Medicaid regulations.[2] The Fifth Circuit's finding that the district court lacked jurisdiction to wade into this morass, absent proper exhaustion of the Vaccine Act remedy, recognizes the Vaccine Court's specialized expertise in deciding qualification issues and prevents deliberate circumvention of that tribunal's statutory authority.

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2. Nonetheless, it was Wyeth's position in the court below that the billing records that were available demonstrated that plaintiffs in fact were qualified to file a Vaccine Court petition at the relevant time.

Finally, plaintiffs' belated and confusing argument regarding the respective roles of Article I and Article III tribunals is a thinly veiled attack on the constitutionality of the Vaccine Act itself. Plaintiffs failed to properly present this argument to the lower court. More important, this argument should have been pursued in Vaccine Court and through the appellate process provided by the Vaccine Act. The argument lacks merit at any rate, since the Vaccine Act on its face provides for review of Vaccine Court decisions, including qualification decisions, by an Article III court. Moreover, the Vaccine Act merely requires claimants to exhaust administrative remedies and does not prevent them from filing a civil suit thereafter.

REASONS FOR DENYING THE PETITION

I. The Petition Does Not Raise An Important Question Of Federal Law, And There Are No Conflicting Rulings To Be Resolved

A. The Fifth Circuit's unpublished opinion applies only to the unusual facts of this case.

The lower court's decision was correct, but even if it were not, it does not merit review because it does not address an important issue of federal law. The decision interprets a repealed portion of the Vaccine Act and would apply only to a limited (if not nonexistent) class of claimants under that statute. The only persons affected would be those (1) whose vaccine-related claims arose before the $1,000 requirement was repealed eight years ago; (2) who allowed the Vaccine Act's limitations period to expire without filing a claim in Vaccine Court; and (3) who seek to litigate the $1,000 issue for the first time in a civil lawsuit so as to avoid application

of the Vaccine Act's tort suit bar. Plaintiffs have not identified any such claimants besides themselves. Wyeth is not aware of any published or unpublished decision involving a plaintiff who attempted to litigate the $1,000 issue outside of Vaccine Court in the first instance. Notably, all of the cases plaintiffs cite in which the $1,000 issue (or any other qualification issue) was disputed were first brought *in Vaccine Court*, not in a civil lawsuit filed without exhausting the Vaccine Act remedy (and also brought years after limitations had run under the Vaccine Act). *See* Petition at 10-14.

B. The Fifth Circuit's decision here does not conflict with that Court's ruling in *Moss*.

In *Moss*, the parents of an allegedly vaccine-injured child filed a civil lawsuit for their own loss of consortium damages (unlike the Romeros who are suing on behalf of their daughter). 381 F.3d at 502-03 & n.1. It was undisputed that the parent plaintiffs in *Moss*, not having received the vaccine themselves, could not qualify to file a Vaccine Court petition. *Id.* at 505 & n.4; *see* 42 U.S.C. § 300aa-11(b)(1)(A). The defendant vaccine manufacturers accordingly conceded that the § 300aa-11(a)(2)(A) tort suit bar did not explicitly bar the parents' individual claims. *See* 381 F.3d at 505. The defendants argued instead that the Vaccine Act as a whole implicitly preempted the parents' individual claims. *See id.* at 505-06. The Fifth Circuit, following *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1 (1st Cir. 1994), rejected this argument. 381 F.3d at 506.

The decision in *Moss* has no bearing on this case. The *Moss* plaintiffs, suing in their individual capacities, were categorically not qualified to file in Vaccine Court, and therefore were not explicitly subject to the tort suit bar, as a

matter of law. The issue was whether the doctrine of implied preemption nonetheless barred their civil lawsuit. In this case, the plaintiffs (as representatives of their daughter) were required to bring their claim for vaccine-related injury in Vaccine Court as an initial matter. The issue here is whether the doctrine of exhaustion of remedies bars plaintiffs asserting a claim for vaccine-related injury from litigating disputed factual issues pertaining to the $1,000 threshold outside Vaccine Court in the first instance.

II. The Fifth Circuit's Ruling Is Correct And Should Not Be Disturbed

A. The Fifth Circuit's decision comports with the Vaccine Act and settled principles of administrative law, and has nothing to do with implied preemption.

The Fifth Circuit correctly rejected plaintiffs' attempted end-run around the Vaccine Act's exhaustion requirement and did not rely on "implied preemption" in doing so. The decision below rests on the doctrine of exhaustion of remedies. The Vaccine Act, properly construed, requires that questions about a claimant's qualification in Vaccine Court be decided in the course of adjudicating all the issues presented in a Vaccine Court petition seeking compensation for vaccine-related injury.

1. The Vaccine Act expressly confers on the Vaccine Court the authority to resolve qualification issues.

As they have throughout the appeal below, plaintiffs invoke the "plain language" of the Vaccine Act in their Petition. *E.g.*, Petition at 7. Yet plaintiffs consistently have ignored § 300aa-13 of that statute. In that provision, Congress

expressly authorizes the Vaccine Court to determine whether a claimant has demonstrated the eligibility criteria of § 300aa-11(c)(1)—which formerly included the $1,000 requirement—by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1)(A). This is an ordinary and expected provision. The tribunal designated to hear a category of disputes necessarily has the power to decide all the predicate issues to its exercise of jurisdiction. The Act contains no provision that sets up other courts as gatekeeper to determine whether any petitioner is qualified to file in Vaccine Court. Indeed, allowing advance adjudication of the Vaccine Court's jurisdiction to hear a particular claim would undermine the Vaccine Act's designation of the Vaccine Court as the tribunal in which claims must be first filed and exhausted.

The proper construction of the Vaccine Act is that questions of qualification must be submitted to the Vaccine Court in the first instance and decided there as part of the petition. One Vaccine Court special master has reached exactly this conclusion with respect to the repealed $1,000 provision:

> [P]ersons who, like petitioner, believe that they have been harmed by a vaccination administered after October 1, 1988, are *required* to file a Program petition, and obtain a resolution of their Program claim, before filing a tort suit against either the vaccine administrator or manufacturer. See § 300aa-11(a)(2). It seems to me that, faced with that requirement, a person in petitioner's situation, with an apparently meritorious claim of a vaccine-related injury, has *no choice* but to file a Program claim and advance the best argument that she can concerning the $1000 requirement,

> even if her argument on that $1000 issue is of questionable merit. Only when her argument concerning the $1000 issue has been advanced and rejected in the Program proceeding is she legally free to pursue a tort claim.

Jessen v. Sec'y of Health & Human Servs., No. 94-1029V, 1997 WL 48940, at *3 (Fed. Cl. Spec. Mstr. Jan. 17, 1997) (emphasis in original).[3]

2. Claimants must present issues regarding an administrative agency's jurisdiction to the agency in the first instance.

The decision below is also supported by uncontroversial principles of administrative law. "Questions of an agency's authority and jurisdiction have long been held by the courts to be particularly appropriate for initial agency determination." *Imperial Carpet Mills, Inc. v. Consumer Prods. Safety Comm'n*, 634 F.2d 871, 874 (5th Cir. 1981) (per curiam). For example, in *Myers v. Bethlehem*

3. Plaintiffs' protest that the decision below would have required them to file a "false" affidavit, Petition at 15-16, is disingenuous. First, when the $1,000 provision was in effect, a petitioner could file in Vaccine Court even before he had incurred $1,000 in qualifying expenses and could supplement his petition with new expenses until the Vaccine Act statute of limitations expired. *Black v. Sec'y of Health & Human Servs.*, 93 F.3d 781, 790 (Fed. Cir. 1996) ("We agree with the special master that the $1000 requirement is 'time-specific,' but we do not think that conclusion bars the special master from accepting a supplemental pleading that would cure a petition that is defective because it was filed before the $1000 expense threshold was reached."). Second, the record below establishes that at the very least plaintiffs had a good faith basis for asserting they had incurred more than $1,000 in qualifying expenses.

Shipbuilding Corp., 303 U.S. 41 (1938), this Court vacated a district court injunction enjoining the National Labor Relations Board ("NLRB") from proceeding with hearings on a complaint of unfair labor practices. The employer contended successfully in the district court that the NLRB lacked jurisdiction to hear the complaint because the complaint did not affect interstate commerce. *See id.* at 47. This Court, however, recognized that the NLRB itself had jurisdiction to determine whether the complaint concerned interstate commerce. *Id.* at 49-50. It then dismissed the employer's contention that the employer should be permitted to litigate the issue in district court in the first instance:

> So to hold would, as the government insists, in effect substitute the District Court for the Board as the tribunal to hear and determine what Congress declared the Board exclusively should hear and determine in the first instance. The contention is at war with the long-settled rule of judicial administration that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted. That rule has been repeatedly acted on in cases where, as here, the contention is made that the administrative body lacked power over the subject matter.

Id. at 50-51 (footnotes omitted). Similarly, the Vaccine Court had the authority to determine any dispute over the plaintiffs' qualification to file in that forum.

This does not mean a court may never evaluate an agency's jurisdiction before the agency has been permitted to pass on the issue, of course. But such intervention is the

exception and not the rule. *See Frito-Lay, Inc. v. Fed. Trade Comm'n*, 380 F.2d 8, 10 (5th Cir. 1967) (per curiam) (only in "extraordinary cases" should claimants be allowed to short-circuit the administrative process for determining the agency's jurisdiction); *see also Gen. Atomics v. U.S. Nuclear Regulatory Comm'n*, 75 F.3d 536, 541 (9th Cir. 1996) (courts generally will consider arguments that an agency or administrative tribunal has no authority to act only when its jurisdiction is "plainly lacking"); *Accion Social de Puerto Rico, Inc. v. Perez*, 831 F.2d 365, 370 (1st Cir. 1987) ("[T]he widely endorsed rule is that an agency should make the initial determination of its own jurisdiction unless this jurisdiction is patently lacking."). The principle that agencies should decide their own jurisdiction in the first instance applies with even greater force where, as here, exhaustion is mandated by statute. "If Congress itself imposes an exhaustion requirement, courts must enforce its express terms." *Fed. Deposit Ins. Corp. v. Scott*, 125 F.3d 254, 257 (5th Cir. 1997) (citing *Coit v. Independence Joint Venture v. Fed. Sav. & Loan Ins. Corp.*, 489 U.S. 561, 579 (1989)).[4] These cases make clear that an administrative tribunal's decision

4. Exhaustion principles apply to administrative tribunals as well as "agencies," and numerous courts have applied exhaustion principles to cases that fell under the initial jurisdiction of the Vaccine Court. *E.g., Shalala v. Whitecotton*, 514 U.S. 268, 270 (1995) ("A claimant alleging that more than $1,000 in damages resulted from a vaccination after the Act's effective date in 1988 must exhaust the Act's procedures and refuse to accept the resulting judgment before filing any *de novo* civil action in state or federal court."); *Evans v. Lederle Labs.*, 167 F.3d 1106, 1108-09 (7th Cir. 1999) ("Congress thus created a bias in favor of the federal compensation scheme by requiring vaccine-injury plaintiffs to exhaust the remedy under the Act before resorting to civil litigation."); *see also Ramirez v. Am. Home Prods.*, No. B-03-144, 2005 WL 2277518, at *7 (S.D. Tex. Sept. 16, 2005) (unpublished opinion) ("Plaintiff has not, however, exhausted her remedies under the Vaccine Act before the Vaccine Court.").

regarding its own jurisdiction is not an advisory opinion, Petition at 18, but a proper exercise of its legitimate authority.

3. This case is not about implied preemption.

Implied preemption is a straw man. The district court and Fifth Circuit found that plaintiffs' failure to first present their case, including the qualification issue, in the Vaccine Court constituted a failure to exhaust administrative remedies that barred the district court from exercising jurisdiction *under the express terms of the statute. See* Pl. App. C, 13a ("Under both the current and pre-1998 ('superceded') versions of the Vaccine Act, section 300aa-11(a)(2)(A) erects a bar to bringing a civil action, unless a claimant first files a claim in the Vaccine Court and exhausts the remedies of the Court."); *see also* Pl. App. B, 5a (stating that district court "determined that it lacked subject matter jurisdiction over [plaintiffs'] suit because [they] failed to file a petition in the Vaccine Court before filing their civil suit in district court" and affirming dismissal). The courts below had no reason to, and did not, find that the Vaccine Act impliedly preempted plaintiffs' claims.

Two related misstatements in plaintiffs' Petition bear mention here. Plaintiffs assert that the district court "accepted as true the Romero's factual contention that Susana had not satisfied the '$1,000' requirement." Petition at 3. Presumably based on this premise, plaintiffs then claim that "[b]oth courts below, held that courts of general jurisdiction lack subject matter jurisdiction to consider personal injury suits, like Susana Romero's, if they involve vaccine injuries because the Vaccine Program constitutes a broad preemption of all vaccine injury claims." Petition at 7. Thus, according to plaintiffs, the district court *presumed* plaintiffs were

unqualified to file in Vaccine Court, and yet still applied the § 300aa-11(a)(2)(A)-(B) tort suit bar to their claims.[5]

Plaintiffs misstate the record and mischaracterize the decisions below. The district court did not presume that plaintiffs were or were not qualified to proceed in Vaccine Court. The court held that it lacked jurisdiction to decide the qualification issue because plaintiffs were required to submit that issue to the Vaccine Court in the first instance as part of a petition seeking compensation for a vaccine-related injury in order to properly exhaust their administrative remedies. Neither the district court nor the Fifth Circuit based its decision on some kind of broad implied preemption, Petition at 7, but on the express terms of the statute construed in accordance with settled exhaustion principles.

B. The Court should not consider plaintiffs' Article III argument because it was not raised below, and because it lacks merit.

Plaintiffs complain that the decision below violates Article III, but the precise contours of their argument are unclear. At one point, they assert the decision "contravenes this Court's doctrine that persons who assert private rights . . . are entitled to jury trials in Article III tribunals." Petition at 16-17. Plaintiffs also cite *United States v. Raddatz*, 447 U.S. 667 (1980), in support of their contention that "if a non-Article III tribunal were to preform [sic] an adjudicative function, like deciding

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5. These misstatements are contradicted by the plaintiffs' own repeated assertions in the court below and in the Petition that the district court abdicated its judicial responsibility to "look[] at the facts," and make a finding on qualification under the Vaccine Act. Petition at 19-20; *see* Appellants' Brief at 16-19 (arguing that the district court had a duty to "adjudicate jurisdictional facts").

whether the Vaccine Program had jurisdiction over a suit or whether jurisdiction properly resides in an Article III court, an Article III court would be obliged to re-determine such a dispute *de novo*." Petition at 5-6. Both of these arguments appear to be attacks on the Vaccine Act itself rather than the decision below.

The Court need not resolve whatever issue the plaintiffs are attempting to raise, however. Plaintiffs did not make their Article III argument to the district court or in their initial brief in the Fifth Circuit. They raised it for the first time in their Petition for Rehearing *En Banc*. A party waives an issue by failing to raise it before the original panel. *See Miller v. Texas Tech Univ. Health Scis. Ctr.*, 421 F.3d 342, 349 & n.17 (5th Cir. 2005) (en banc); *Hightower v. Texas Hosp. Ass'n*, 73 F.3d 43, 43 (5th Cir. 1996). Plaintiffs have not demonstrated any exceptional circumstances warranting review by this Court of an issue they did not properly present in the court below. *See Clingman v. Beaver*, 544 U.S. 581, 597-98 (2005) (declining to hear constitutional challenge to state election laws that was not raised or addressed below because there were no unusual circumstances warranting such review). The Court therefore should decline to consider this argument.

Plaintiffs' Article III complaints lack merit in any event. The Vaccine Act provides for review of the Vaccine Court's findings of fact and conclusions of law by appeal to the Federal Circuit. 42 U.S.C. § 300aa-12(f). That court determines matters of jurisdiction *de novo*. *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1309 (Fed. Cir. 1999). Moreover, the Vaccine Act merely requires exhaustion of administrative remedies; it does not foreclose a civil lawsuit and jury trial thereafter. 42 U.S.C. § 300aa-21(a).

Requiring claimants to present the qualification issues to the Vaccine Court before attempting to litigate them in civil court raises no Article III concerns. If, for example, the Vaccine Court had found these plaintiffs unqualified under the Vaccine Act, they would then have been free to file a civil lawsuit or to pursue appellate review of the qualification decision. 42 U.S.C. §§ 300aa-12(f), 300aa-21(a)(2); *see, e.g.*, *Black v. Sec'y of Health & Human Servs.*, 93 F.3d 781, 789-92 (Fed. Cir. 1996) (affirming in part and reversing in part qualification determinations by the Vaccine Court). If they were deemed qualified, plaintiffs could have rejected the Vaccine Court's decision on the merits (with or without first pursuing appellate relief) and filed a civil lawsuit under § 300aa-21(a)(1). The Vaccine Act afforded plaintiffs every opportunity to obtain Article III review of their claims, including the qualification issue. They simply failed to do so.

Finally, to the extent plaintiffs are attacking the constitutionality of the Vaccine Act, these concerns could and should have been raised in the Vaccine Court itself. The Court of Federal Claims and its adjunct special masters possess the jurisdictional authority to consider constitutional challenges to the Vaccine Act, subject to review by the Federal Circuit. *Terran*, 195 F.3d at 1309-10. Plaintiffs accordingly should not be allowed to preemptively or collaterally raise such issues in this Court, outside of the Vaccine Act. *Cf. Fed. Communications Comm'n v. ITT World Communications, Inc.*, 466 U.S. 463, 468-69 (1984) (district court lacked jurisdiction to rule on propriety of FCC action before completion of statutory review procedure that provided for appeal to the Court of Appeals).

CONCLUSION

For the foregoing reasons, Wyeth requests that the Court deny the Petition for Writ of Certiorari.

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In The

Supreme Court of the United States

FIDEL ROMERO, Next Friend of Susana Romero, a minor; ANDREA ROMERO, Next Friend of Susana Romero, a minor,

Petitioners,

v.

WYETH, previously known as Lederle Laboratories

Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

REPLY BRIEF FOR PETITIONERS

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List of Parties

The names of all parties to the proceedings in the court whose judgement is sought to be reviewed here appear in the caption of the case. There is no parent or subsidiary company of any party to be listed.

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REPLY BRIEF FOR PETITIONERS

The respondent states, at page 15 of its brief, that Susana Romero failed to raise her Article III constitutional argument until her Petition for Rehearing *En Banc* was filed with the Fifth Circuit Court of Appeals. That statement is false. Susana Romero's principle brief to the Fifth Circuit included a section entitled "Constitutional Considerations," which contained her Article III argument. The following is one paragraph from that section.

> *Garner* foreshadows the clear distinction later drawn between "private rights" and "public rights." 346 U.S. at 496-97. Years later, in a line of cases, the most notable of which is *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33 (1989), the Supreme Court indicated that Congress could not assign the adjudication of a "private right," *e.g.*, an action involving a "wholly private tort," to a non-Article III judicial body, in derogation of the right to a jury trial under the Seventh Amendment.

Respondent also mentions, but does not elaborate, that Susana Romero failed to raise this constitutional argument at the district court level. However, as respondent knows, the district court never provided the parties an opportunity to address this issue. Respondent filed a F.R.C.P. 12(b)(6) motion, not a 12(b)(1) motion. The district court ordered the parties to conduct discovery in accordance with respondent's 12(b)(6) motion. The

actions by the district court, of course, led Susana Romero to believe that the district court understood that it had jurisdiction over her cause of action since she was asserting a "private right." It was not until after the district court had this case for twenty one months and discovery, briefing and oral argument had concluded, that the district court issued its Order wherein the court, *sua sponte*, converted respondent's 12(b)(6) motion into a 12(b)(1) Order and informed the parties for the first time that the court decided that it lacked jurisdiction.

Respondent makes the argument at page 9 of its brief, that there are no provisions in the Vaccine Act that set up other courts as gate keepers for Vaccine Program claims. This appeal is not about setting up gatekeepers for the Vaccine Program. Petitioner has never advocated such a position.

Respondent, at pages 9 - 10, cites *Jessen v. Sec'y of Health & Human Servs.*, No. 94-1029V, 1997 WL 48940, at *3 (Fed. Cl. Spec. Mstr. Jan. 17, 1997). *Jessen* is an attorney's fees decision where the special master is being asked to apply the "good faith" and "reasonable basis" standards from 42 U.S.C. § 300aa-15(e)(1)(B), to a request for attorney's fees. The special master does point out that special master decisions create no precedent, in or out of the Vaccine Program, when he states that "[l]egal precedent under the Program is only legally binding when established by the United States Court of Appeals for the Federal Circuit." *Jessen*, 1997 WL 48940 at *3. More importantly, in writing this attorney's fees decision the special master did not address the effect of the savings

provision, 42 U.S.C. § 300aa-11(a)(9), on a person who is not qualified to access the Vaccine Program. This is not at all surprising since subsection 11(a)(9) is to be applied by district court judges, not special masters.

Respondent, at page 12, n. 4, cites a decision from this Court, *Shalala v. Whitecotton*, 514 U.S. 268 (1995). The *Whitecotton* case was an appeal from the Vaccine Program and addresses the issue of what constitutes a sign or symptom of an injury for the purpose of establishing a "Table" injury. The sentence which respondent chose to reproduce is from a brief history of the Vaccine Act that appears at the beginning of the decision. It is not the holding of the case. The *Whitecotton* decision did not address the issue which is before the Court, which is, if a vaccine injured person is not "qualified" to access the Vaccine Program, as that term is defined by 42 U.S.C. § 300aa-11(c)(1), does the savings provision, 42 U.S.C. § 300aa-11(a)(9), allow them to prosecute their civil case in a court of general jurisdiction without first going through the Vaccine Program. Not only did the *Whitecotton* decision not address the savings provision, 42 U.S.C. § 300aa-11(a)(9), neither did respondent's brief. Respondent managed to write its Brief in Opposition without once referring to subsection 11(a)(9).

The Vaccine Program is an important Federal program. It effects every person in this Country that receives vaccines. Respondent argues, at pages 6 - 7, that the only person that would be effected by review of this case would be Susana Romero. That is not true. Every person who suffers a vaccine related injury in the future,

and who has suffered a vaccine injury in the past, that is not "qualified" to access the Vaccine Program, as that term is defined by 42 U.S.C. § 300aa-11(c)(1), is adversely effected by the decisions below. The district court's decision and the Fifth Circuit's decision have written the savings provision, 42 U.S.C. § 300aa-11(a)(9), out of the Vaccine Act.

The decisions below have also eroded the authority of Article III judges. Article III judges must be free to examine the facts of cases in their courts to determine if they have jurisdiction. Those jurisdictional determinations cannot be abdicated to an Article I special master.

CONCLUSION

The petition for writ of certiorari should be granted.

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